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AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
1772	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,214	TANAKA, HAYAO	
	Examiner	Art Unit	
	Walter B Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The amendments made to claims 4-7 provided on page 2 of Applicant's Amendment (Paper #9) have been received and considered by Examiner.

2. The cancellation of claims 1-3 and 8-11 on page 2 of Paper #9 has been acknowledged by Examiner.

3. New claim 12 provided on page 2 of Paper #9 has been received and considered by Examiner.

WITHDRAWN OBJECTIONS

4. The objection to claims 8-11 made of record in paragraph 1 on page 2 of Paper #5 has been withdrawn due to Applicant's amendments made in Paper #9.

WITHDRAWN REJECTIONS

5. The 35 U.S.C. 112, first paragraph rejection of claims 1-7 made of record in paragraph 3 on page 2 of Paper #5 has been withdrawn due to Applicant's amendments and arguments made on page 7 of Paper #9. Examiner, however, wishes to make it clear on the record that Examiner disagrees with Applicant's statement that "Applicants submit [that] the saturation adsorption amount is, in fact, a function of the container and are defined by the ultra-hydrophilic polymer selected for coating the container". The saturation adsorption amount is not solely a function of the material used as the inner coating of the container. This matter is further discussed in the *ANSWERS TO APPLICANT'S ARGUMENTS* section below in regard to the 35 U.S.C. 112, second paragraph rejection of claims 1 and 7.

6. The 35 U.S.C. 112, second paragraph rejection of claims 1-6 made of record in paragraph 5 on pages 3-4 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

7. The 35 U.S.C. 102(b) rejection of claims 1-7 as anticipated by Fox made of record in paragraph 7 on pages 4-5 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

8. The 35 U.S.C. 102(b) rejection of claims 1-7 as anticipated by Levy et al. made of record in paragraph 8 on page 5 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

9. The 35 U.S.C. 102(b) rejection of claims 1-7 as anticipated by Buechler made of record in paragraph 9 on pages 5-6 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

10. The 35 U.S.C. 102(b) rejection of claims 1-7 as anticipated by Oberhardt made of record in paragraph 10 on pages 6-7 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

11. The 35 U.S.C. 103 rejection of claims 1 and 7 over Fox in view of applicant's admission made of record in paragraph 12 on page 8 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

12. The 35 U.S.C. 103 rejection of claims 1 and 7 over Levy et al. in view of applicant's admission made of record in paragraph 13 on pages 8-9 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

13. The 35 U.S.C. 103 rejection of claims 1 and 7 over Buechler in view of applicant's admission made of record in paragraph 14 on page 9 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

14. The 35 U.S.C. 103 rejection of claims 1 and 7 over Oberhardt in view of applicant's admission made of record in paragraph 15 on pages 9-10 of Paper #5 has been withdrawn due to Applicant's amendments in Paper #9.

REPEATED REJECTIONS

15. The 35 U.S.C. 112, second paragraph rejection of claim 7 in regard to the saturation absorption amount has been repeated for the reasons previously made of record in paragraph 5 on pages 3 and 4 of Paper #5.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

16. Claims 4, 5 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 12, the chemical structure intended to be recited by the term "polyoxy(C2-C9 alkylene group-containing methacrylate) polymer" is unclear. Is this an ether? Or does the "oxy" in "polyoxy" refer to the oxygen in the acrylate? What is "containing" intended to mean in regard to the chemical structural relationship between the alkylene group and the methacrylate? Furthermore, "phopholipid" is misspelled. Furthermore, the phrase "the saturation adsorption amount of molecules used for the assay is $1X10^{-1}$ pmol/cm^2 or less" is indefinite because the recitation of a saturation absorption amount does not establish the meets

and bounds of the claim, since the molecule used for the assay, the solution used for the assay and the concentration of the particular molecule in the solution used for the assay are determining factors in the saturation absorption amount of a given material (as previously made of record on page 3 of Paper #5) in addition to the temperature at which the assay is conducted and the pH of the solution (page 7 of Applicant's specification). Furthermore, the portion of the inner surface of the container that this saturation adsorption amount is being claimed for is unclear- is this an average over the entire inside surface of the container, or is this amount intended for only a portion of the inside of the container? If the amount is intended for only a portion of the container, the structure of this portion, including the physical bounds of the portion, must be associated with this amount in the claim. The recitation "at least an inner surface of the container" indicates that there is more than one inner surface of the container and that only one surface need be formed from or coated with the ultra-hydrophilic polymer.

In regard to claims 4 and 5, claims 4 and 5 are broader than claim 12. The specification defines "an ultra-hydrophilic polymer" as a polymer that forms an inner surface of the container having a contact angle between the surface and water of 1° or less (page 12, lines 5-10).

Claim Rejections - 35 USC § 103

17. Claims 4-7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox in view of Clausen et al. and in further view of Applicant's admitted prior art.

In regard to claim 12, Fox teaches a reaction well with a bottom wall that has an inner surface that is hydrophilic and side walls that have hydrophobic inner walls (col. 2, lines 15-29). Fox teaches that the reaction well is for conducting an immunogenic reaction (col. 3, lines 22-25); therefore, Fox teaches a container for an immunoassay. Fox teaches that the bottom of the

well is coated with a hydrophilic material or the inner surface 32 of the bottom wall 28 is made from a hydrophilic plastic (col. 2, lines 25-30 and Figure 4); Fox therefore teaches that at least an inner surface of the container is formed from or coated with a hydrophilic polymer. The hydrophilic polymer is necessarily insoluble in water; the inner surface of a container for an immunoassay, or a container for any application that requires the container to hold any aqueous liquid, is necessarily formed of a polymer that is insoluble in water so that the polymer does not dissolve in the solution the container contains. Fox fails to teach that the hydrophilic polymer is an ultra-hydrophilic polymer that is selected from the group of polymer species listed in the claim and that the saturation absorption amount of molecules used for the assay is 1×10^{-1} pmol/cm^2 or less. Clausen et al., however, disclose a hydrophobic membrane for a sensor for measuring an analyte in a biological sample having a surface that is coated with a hydrophilic component in order to provide a hydrophilic character to the surface of the membrane so that the tendency of macromolecules, such as those in blood, to stick to the surface of the membrane is minimized so that more accurate measurements are attained (col. 1, lines 5-41, col. 2, lines 5-11 and col. 3, lines 5-19). Clausen et al. disclose that polyvinyl pyrrolidone is a suitable hydrophilic component (col. 3, lines 5-16). Therefore, one of ordinary skill in the art would have recognized to have used the ultra-hydrophilic polymer, polyvinyl pyrrolidone, as the hydrophilic polymer of Fox in order to provide a hydrophilic character to the inner surface of the container of Fox so that the tendency of macromolecules to stick (i.e. adsorb) to the inner surface of the container of Fox is minimized as taught by Clausen et al., and since polyvinyl pyrrolidone is a notoriously well known hydrophilic polymer as taught by Clausen et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the ultra-hydrophilic polymer, polyvinyl pyrrolidone, as the hydrophilic polymer of Fox in order to provide a hydrophilic character to the inner surface of the container of Fox so that the tendency of macromolecules to stick (i.e. adsorb) to the inner surface of the container of Fox is minimized as taught by Clausen et al., and since polyvinyl pyrrolidone is a notoriously well known hydrophilic polymer as taught by Clausen et al.

In further regard to claim 12 and also in regard to claim 7, Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm^2 or more and that the adsorption amount varies in accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container (page 6, line 26-page 7, line 6 of applicants' specification). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal type of molecule, and the optimal concentration range of the particular molecule in solution, in order to achieve the claimed saturation adsorption amount for the inner surface of the container formed from or coated with the hydrophilic polymer of Fox through routine experimentation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The recitation "for an immunoassay" is an intended use phrases that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQd 1647 (1987).

The limitation "coated with" (second line of claim 12) has not been given patentable weight since the method of forming the container is not germane to the issue of patentability of the container itself.

In regard to claims 4-6, Fox teaches that an aqueous solution spread relatively evenly across the bottom of the wells in all samples tested (col. 8, lines 20-23); therefore, the contact angle of the aqueous solution on the bottom of the well approaches a contact angle of zero, a condition which reads on the claimed contact angle values "30° or less", "15° or less" and "1° or less" of claims 4-6.

18. Claims 4-7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. in view of Clausen et al. and in further view of Applicant's admitted prior art.

Levy et al. teach a hydrophobic cuvette, the inner surface of which is coated with a hydrophillic polymer (col. 4, lines 41-45). The hydrophilic polymer is necessarily insoluble in water; the inner surface of a container for any application that requires the container to hold any aqueous liquid is necessarily formed of a polymer that is insoluble in water so that the polymer does not dissolve in the solution the container contains. Levy et al. fail to teach that the hydrophilic polymer is an ultra-hydrophilic polymer that is selected from the group of polymer species listed in the claim and that the saturation absorption amount of molecules used for the assay is 1×10^{-1} pmol/cm^2 or less. Clausen et al., however, disclose a hydrophobic membrane for a sensor for measuring an analyte in a biological sample having a surface that is coated with a hydrophilic component in order to provide a hydrophilic character to the surface of the membrane so that the tendency of macromolecules, such as those in blood, to stick to the surface of the membrane is minimized so that more accurate measurements are attained (col. 1, lines 5-

41, col. 2, lines 5-11 and col. 3, lines 5-19). Clausen et al. disclose that polyvinyl pyrrolidone is a suitable hydrophilic component (col. 3, lines 5-16). Therefore, one of ordinary skill in the art would have recognized to have used the ultra-hydrophilic polymer, polyvinyl pyrrolidone, as the hydrophilic polymer of Levy et al. in order to provide a hydrophilic character to the inner surface of the container of Levy et al. so that the tendency of macromolecules to stick (i.e. adsorb) to the inner surface of the container of Levy et al. is minimized as taught by Clausen et al., and since polyvinyl pyrrolidone is a notoriously well known hydrophilic polymer as taught by Clausen et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the ultra-hydrophilic polymer, polyvinyl pyrrolidone, as the hydrophilic polymer of Levy et al. in order to provide a hydrophilic character to the inner surface of the container of Levy et al. so that the tendency of macromolecules to stick (i.e. adsorb) to the inner surface of the container of Levy et al. is minimized as taught by Clausen et al., and since polyvinyl pyrrolidone is a notoriously well known hydrophilic polymer as taught by Clausen et al.

In further regard to claim 12 and also in regard to claim 7, Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm^2 or more and that the adsorption amount varies in accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container (page 6, line 26-page 7, line 6 of applicants' specification). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal type of molecule, and the optimal

concentration range of the particular molecule in solution, in order to achieve the claimed saturation adsorption amount for the inner surface of the container formed from or coated with the hydrophilic polymer of Levy et al. through routine experimentation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The recitation "for an immunoassay" is an intended use phrases that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQd 1647 (1987).

The limitation "coated with" (second line of claim 12) has not been given patentable weight since the method of forming the container is not germane to the issue of patentability of the container itself.

In regard to claims 4-6, the contact angle between the inner surface of the container made of polyvinyl pyrrolidone and water is necessarily 1° or less since polyvinyl pyrrolidone is an ultra-hydrophilic polymer as claimed by Applicants, and since the specification defines "an ultra-hydrophilic polymer" as a polymer that forms an inner surface of the container having a contact angle between the surface and water of 1° or less (page 12, lines 5-10).

19. Claims 4-7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler in view of Clausen et al. and in further view of Applicant's admitted prior art.

Buechler teaches a diagnostic device with time gate 5 leading into reaction chamber 4 (col. 7, lines 41-42 and Figure 1B) for an immunoassay (col. 8, line 39). The time gate is a

capillary channel with hydrophobic surfaces (col. 7, lines 58-67) and serves as a barrier to a hydrophilic liquid (col. 7, lines 53-58). The hydrophobic barrier is changed to a hydrophilic zone when a certain component of the reaction mixture binds to the hydrophobic capillary channel walls (col. 8, lines 7-10). Buechler teaches that this component is chosen from various proteins, polypeptides or polymers (col. 8, lines 17-23). The hydrophobic surface of the capillary channel is therefore coated with a hydrophilic polymer to enable the hydrophilic reaction mixture to flow through the capillary. Buechler fails to teach that the hydrophilic polymer is an ultra-hydrophilic polymer that is selected from the group of polymer species listed in the claim and that the saturation absorption amount of molecules used for the assay is 1×10^{-1} pmol/cm^2 or less. Clausen et al., however, disclose a hydrophobic membrane for a sensor for measuring an analyte in a biological sample having a surface that is coated with a hydrophilic component in order to provide a hydrophilic character to the surface of the membrane so that the tendency of macromolecules, such as those in blood, to stick to the surface of the membrane is minimized so that more accurate measurements are attained (col. 1, lines 5-41, col. 2, lines 5-11 and col. 3, lines 5-19). Clausen et al. disclose that polyvinyl pyrrolidone is a suitable hydrophilic component (col. 3, lines 5-16). Therefore, one of ordinary skill in the art would have recognized to have used the ultra-hydrophilic polymer, polyvinyl pyrrolidone, as the hydrophilic polymer of Buechler in order to provide a hydrophilic character to the inner surface of the container of Buechler so that the tendency of macromolecules to stick (i.e. adsorb) to the inner surface of the container of Buechler is minimized as taught by Clausen et al., and since polyvinyl pyrrolidone is a notoriously well known hydrophilic polymer as taught by Clausen et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the ultra-hydrophilic polymer, polyvinyl pyrrolidone, as the hydrophilic polymer of Buechler in order to provide a hydrophilic character to the inner surface of the container of Buechler so that the tendency of macromolecules to stick (i.e. adsorb) to the inner surface of the container of Buechler is minimized as taught by Clausen et al., and since polyvinyl pyrrolidone is a notoriously well known hydrophilic polymer as taught by Clausen et al.

In further regard to claim 12 and also in regard to claim 7, Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm^2 or more and that the adsorption amount varies in accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container (page 6, line 26-page 7, line 6 of applicants' specification). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal type of molecule, and the optimal concentration range of the particular molecule in solution, in order to achieve the claimed saturation adsorption amount for the inner surface of the container formed from or coated with the hydrophilic polymer of Buechler through routine experimentation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The recitation "for an immunoassay" is an intended use phrases that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQd 1647 (1987).

The limitation "coated with" (second line of claim 12) has not been given patentable weight since the method of forming the container is not germane to the issue of patentability of the container itself.

In regard to claims 4-6, the contact angle between the inner surface of the container made of polyvinyl pyrrolidone and water is necessarily 1° or less since polyvinyl pyrrolidone is an ultra-hydrophilic polymer as claimed by Applicants, and since the specification defines "an ultra-hydrophilic polymer" as a polymer that forms an inner surface of the container having a contact angle between the surface and water of 1° or less (page 12, lines 5-10).

20. Claims 4-7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt in view of Applicant's admitted prior art.

In regard to claims 12 and 7, Oberhardt teaches a reaction slide 1 with reaction volume 66 for performing an immunoassay (col. 13, lines 3-7, col. 38, line 25 and Figure 31). Oberhardt teaches the treatment of the internal surfaces of the reaction slide to increase the hydrophillic character of the internal surfaces of the reaction slide and to therefore decrease the contact angle (col. 14, lines 21-27). Oberhardt teaches the use of polyoxyethylene derivative type and polyoxyethylene ether type surfactants as polymeric wetting agents to decrease the contact angle of the internal surfaces of the reaction slide (col. 14, lines 28-41). The "polyoxy(C2-C9 alkylene group-containing methacrylate) polymer" species claimed in claim 12 is a polyoxyethylene ether type polymer. Oberhardt teaches that the surface properties of the materials should be such that appropriate wetting of the surface, which is indicated by a low contact angle, is achieved to provide proper flow conditions (col. 14, lines 58-63). Oberhardt fails to teach that the saturation absorption amount of molecules used for the assay is 1×10^{-1} pmol/cm^2 or less. Applicants

disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm^2 or more and that the adsorption amount varies in accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container (page 6, line 26-page 7, line 6 of applicants' specification). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal type of molecule, and the optimal concentration range of the particular molecule in solution, in order to achieve the claimed saturation adsorption amount for the inner surface of the container formed from or coated with the hydrophilic polymer of Oberhardt through routine experimentation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The recitation "for an immunoassay" is an intended use phrases that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQd 1647 (1987).

The limitation "coated with" (second line of claim 12) has not been given patentable weight since the method of forming the container is not germane to the issue of patentability of the container itself.

In regard to claims 4-6, the contact angle between the inner surface of the container made of polyoxyethylene ether type polymeric wetting agents and water is necessarily 1° or less since polyoxyethylene ether type polymeric wetting agents of the "polyoxy(C2-C9 alkylene group-

containing methacrylate) polymer" type are ultra-hydrophilic polymers as claimed by Applicants, and since the specification defines "an ultra-hydrophilic polymer" as a polymer that forms an inner surface of the container having a contact angle between the surface and water of 1° or less (page 12, lines 5-10).

ANSWERS TO APPLICANT'S ARGUMENTS

21. Applicant's arguments on the bottom of page 7-page 8 of Paper #9 regarding the 35 U.S.C. 112, second paragraph rejection of claims 1 and 7 have been fully considered but are not persuasive.

How can "Applicants submit that the saturation adsorption amount is, in fact, a function of the container and not of the molecules to be placed in the container as the Examiner has asserted" as Applicants state in lines 1-3 of page 8 of Paper #9 when Applicant's specification plainly states that "the adsorption amount varies in accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container" (page 7, lines 3-6 of Applicant's specification) and that "the adsorption amount of molecules contained in a solution varies with the identity of the molecules, temperature, concentration of the solution..." (page 7, lines 18-20 of Applicant's specification)? Applicant's statement that "the saturation adsorption amount is, in fact, a function of the container and not of the molecules to be placed in the container as the Examiner has asserted" (lines 1-3 of page 8 of Paper #9) contradicts the above-cited statements made in Applicant's specification. The saturation adsorption amount is a function of the material used as the inner coating of the container AND the particular molecule in solution as established in Applicant's specification. Furthermore, one of ordinary skill in the art is more than well aware that the saturation

adsorption amount is dependent on the nature and degree of the electrostatic interaction between the molecules in solution and the material used as the inner coating of the container, which is necessarily a function of both the particular material used as the inner coating of the container AND the particular molecule in solution, among other factors such as the concentration of the particular molecule in solution as established by Applicant in Applicant's specification and as is also more than well known by those of ordinary skill in the art.

In regard to Applicant's statement that the claimed saturation adsorption amounts (in claim 1 -now 12- and 7) are "not merely arbitrarily selected", Examiner wishes to make it clear on the record that this statement is made in response to the following statement made in paragraph 3 of Paper #5 in the 35 U.S.C. 112, first paragraph rejection of claims 1 and 7: "the claimed saturation adsorption amounts of claims 1 and 7 seem to be arbitrary", which renders Applicant's statement that the claimed amounts are "not merely arbitrarily selected" moot in terms of consideration of the 35 U.S.C. 112, second paragraph rejection of claims 1 and 7. However, the recitation of the saturation adsorption amount ranges in claims 12 and 7 render claims 12 and 7 indefinite because the scope of the claim cannot be ascertained. The recitation of a saturation absorption amount does not establish the meets and bounds of the claim, since the molecule used for the assay, the solution used for the assay and the concentration of the particular molecule in the solution used for the assay are determining factors in the saturation absorption amount of a given material (as previously made of record on page 3 of Paper #5) in addition to the temperature at which the assay is conducted and the pH of the solution (page 7 of Applicant's specification). The claimed saturation adsorption amounts of claims 1 and 7, taken along with claims 1 and 7, do not constitute a patentable distinction from the prior art of record

because one of ordinary skill in the art would have recognized to have adjusted the appropriate factors which collectively determine the saturation absorption amount as previously made of record on page 3 of Paper #5.

Examiner wishes to make it clear on the record that Applicant's statement that "the present invention is amenable to a diverse array of structures, so long as the inner surface (the surface to contact the immunoassay specimen) is formed from or coated with the claimed ultra-hydrophilic polymers" (second full paragraph on page 8) includes a statement that is not commensurate with the structure recited in claim 12. Claim 12 does not recite that "THE inner surface (the surface to contact the immunoassay specimen) is formed from or coated with the claimed ultra-hydrophilic polymers", but that "at least an inner surface of the container is formed from or coated with an ultra-hydrophilic polymer". This is pointed out in support of the 35 U.S.C. 112, second paragraph rejection to claim 12 made in this Office Action (Paper #10).

22. Applicant's arguments on pages 3-7 of Paper #9 regarding the 35 U.S.C. 102 and 35 U.S.C. 103 rejections of record in Paper #5 are rendered moot due to the new 35 U.S.C. 103 rejections made of record in this Office Action (Paper #10) as necessitated by amendment.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B Aughenbaugh whose telephone number is 703-305-4511. The examiner can normally be reached on Monday-Friday from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 703-308-4251. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

wba
04/30/03 WBA

HAROLD PYON
SUPERVISORY PATENT EXAMINER
5/1/03